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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,669	01/30/2001	Theoharis C. Theoharides	51275/107	8174

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EXAMINER

EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/02/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/771,669

Applicant(s)

THEOHARIDES, THEOHARIS C.

Examiner

Charesse L. Evans

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 22-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 24-35 is/are rejected.
- 7) ☒ Claim(s) 10 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's petition to revive an abandoned application, filed January 7, 2003. Applicant's petition was granted on January 24, 2003.

Acknowledgement is made of the receipt of applicant's amendment and remarks, filed January 7, 2003.

Applicant's arguments, with respect to the rejection(s) of claim(s) 1-9, 11-13 and 24-35 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Claims 1-13 and 22-35 are active in the action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-9, 11-13 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 5,804,594) in view of Arora (US 5,223,257). The claims are directed to compositions with synergistic anti-inflammatory effects composed of a proteoglycan, and unrefined kernel oil and one or more of a D-hexosamine sulfate, a flavonoid, S-adenosylmethionine, and a histamine-1-receptor antagonist.

Murad teaches a pharmaceutical composition for treating unhealthy skin comprising glucosamine sulfate, chondroitin sulfate and quercetin (column 4, lines 1-31, 50 and column 10-11, Example 3). The referenced composition may be presented as discrete units such as capsules, tablets, aerosol sprays, creams, pastes, gels, solutions, dispersions, suspensions in an aqueous liquid, a non-aqueous liquid, or ointments (column 9, lines 33-49). Daily dosages range from 10mg to 20,000 mg, wherein the glucosamine sulfate is about 3-17%, the chondroitin sulfate is about 3-17% and the quercetin is about 0.5-5% (column 8, lines 12-26). The composition also includes at least one amino acid present in an amount of about 2 to 25 weight percent (column 6, lines 9-18). The composition may be administered via a variety of routes including oral, topical and transdermal (column 8, lines 43-52). In one embodiment, the composition may further comprise other therapeutic ingredients such as vitamin E (column 4, line 18).

Murad does not teach the inclusion of unrefined olive oil within its composition, however, Arora supplies this deficiency by disclosing an anti-

inflammatory topical composition comprising pure, virgin, olive oil (column 1, line 35 and column 2, lines 13-14).

The cited references do not expressly teach that the proteoglycan or chondroitin sulfate be of non-bovine origin. It is the position of the examiner that this feature does not impart a patentable characteristic, absent a showing of criticality. The presence of the proteoglycan or condroitin sulfate is all that is needed to render obvious applicant's claims. In a composition, patentable weight is not given to the origin or reason for including a component, as long as all of the necessary components are present. Furthermore, when a component is included in a composition, all of its properties and advantages are inherent to the composition.

One of ordinary skill in the art would be motivated to combine the teachings of Murad and Arora because both references teach utilizing its compositions to address inflammation. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murad (US 5,804,594) and Arora (US 5,223,257) in view of Florio (US 6,136,795). Murad

does not teach its composition used for inflammation, however, Florio teaches a dietary regimen of nutritional supplements which provides symptomatic relief from arthritis composed of a mixture of chondroitin sulfate and glucosamine sulfate (Abstract).

Florio does not expressly teach a specific isomer of the glucosamine sulfate, however, absent a showing of criticality or unexpected results, it is the position of the examiner that this is a limitation that would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable. The results must be those that accrue from the specific limitation.

It would have been prima facie obvious to a person of ordinary skill in the art, at the time of the claimed invention to further use the claimed composition to address inflammatory disease states. A person of ordinary skill in the art would have been motivated to include this additional use because chondroitin sulfate and glucosamine sulfate are known to be useful for treating inflammatory conditions.

Claim Objections

Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Charesse L. Evans
Examiner
Art Unit: 1615

September 29, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600